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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/697,894      | 10/30/2003  | Joseph A. Beavo      | 27866/39701         | 9227             |

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MARSHALL, GERSTEIN & BORUN LLP  
233 S. WACKER DRIVE, SUITE 6300  
SEARS TOWER  
CHICAGO, IL 60606

EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/697,894

Applicant(s)

BEAVO ET AL.

Examiner

Elizabeth Slobodyansky, PhD

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This application is a divisional of application 09/883,825 now US 6,642,040.

The preliminary amendment filed concurrently with the application on October 30, 2003 canceling claims 1-38 and adding claims 39-42 has been entered.

Claims 39-42 are pending.

### ***Information Disclosure Statement***

This application contains no IDS.

### ***Specification***

The disclosure is objected to because of the following: On page 14 before line 4, the heading "Brief Description of the drawing" should be inserted.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for Patent Applications containing nucleotide sequence and/or amino acid sequence disclosures.

37 CFR 1.821(d) requires the use of assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences.

The following are examples of noncompliance where the sequence containing more than four amino acids or ten nucleotides are given without a sequence identifier:

sequences presented in Figure 1. The sequence identifier must be used, either in the drawing or in the Brief Description of the Drawings.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

the claimed invention is directed to non-statutory subject matter.

Claims 41 and 42 are drawn to "The polypeptide product of the expression in a transformed prokaryotic or eukaryotic host cell of a polynucleotide sequence encoding a mammalian cGMP stimulated cyclic nucleotide phosphodiesterase as set forth in SEQ ID NO:39" and "The polypeptide product of the expression in a transformed prokaryotic or eukaryotic host cell of a polynucleotide sequence encoding a mammalian cGMP stimulated cyclic nucleotide phosphodiesterase as set forth in SEQ ID NO:43", respectively. SEQ ID NO:39 is the amino acid sequence of cGS PDE from bovine adrenal cells. SEQ ID NO:43 is the amino acid sequence of cGS PDE from bovine brain cells. Said cells and the product they express are indistinguishable from the transformed bovine cells expressing the same product. Amending the claims to recite "An isolated and purified polypeptide product", for example, would obviate this rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Martins et al.

Martins et al. (JBC, 1982, Vol. 257, pages 1973-1979) teach purification to homogeneity and characterization of cGMP stimulated PDE from bovine adrenals (abstract, page 1975). The enzyme appears to have the same molecular weight as the enzyme having the amino acid sequence of SEQ ID NO:39. the amino acid sequence is an inherent property of a protein.

**NOTE:**

SEQ ID NO: 39 is first disclosed in the prior application 07/688,356 filed April 19, 1991 (as SEQ ID NO:35).

SEQ ID NO: 43 is first disclosed in the prior application 07/872,644 filed April 20, 1992.

Claims 40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Murashima et al.

Murashima et al. (Biochemistry, June 5, 1990, Vol. 29, pages 5285-5292) teach purification to homogeneity and characterization of cGMP stimulated PDE from bovine brain cerebral cortex (abstract, page 5288, Table I). They teach that molecular mass of enzyme from bovine brain is slightly greater than from adrenals (the sentence bridging pages 5288-5289; page 5289). Absent evidence to the contrary, the enzyme taught by Murashima et al. is the enzyme disclosed in the instant application as having the amino acid sequence of SEQ ID NO: 43. The amino acid sequence is an inherent property of a protein.

Because SEQ ID NO:39 and SEQ ID NO:43 have different priority dates, *supra*, claims 39, 41 and claims 40,42 are rejected below under different statutes over Manganiello et al.

Claims 39 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Manganiello et al.

Claims 40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Manganiello et al.


Manganiello et al. (November 1990) teach cGMP stimulated PDEs purified to homogeneity from bovine adrenals and brains and their properties (pages 63-65). They teach that molecular mass of enzyme from bovine brain is slightly greater than from adrenals (page 65; page 66, Table 3.1). Absent evidence to the contrary, these are same enzymes that have the amino acid sequence of SEQ ID NOs:39 and 43. the

enzymes disclosed by Manganiello et al are purified to apparent homogeneity from the same source and appear to have the same properties as the claimed enzymes. The amino acid sequence is an inherent property of a protein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Elizabeth Slobodyansky, PhD  
Primary Examiner  
Art Unit 1652

June 24, 2005